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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,867	02/15/2006	Chad Munro	8932-1036-999	5650
51832	7590	06/22/2007		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER YANG, ANDREW	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 06/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/518,867

Applicant(s)

MUNRO ET AL.

Examiner

Andrew Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 18, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicants' amendment received on March 29, 2007.

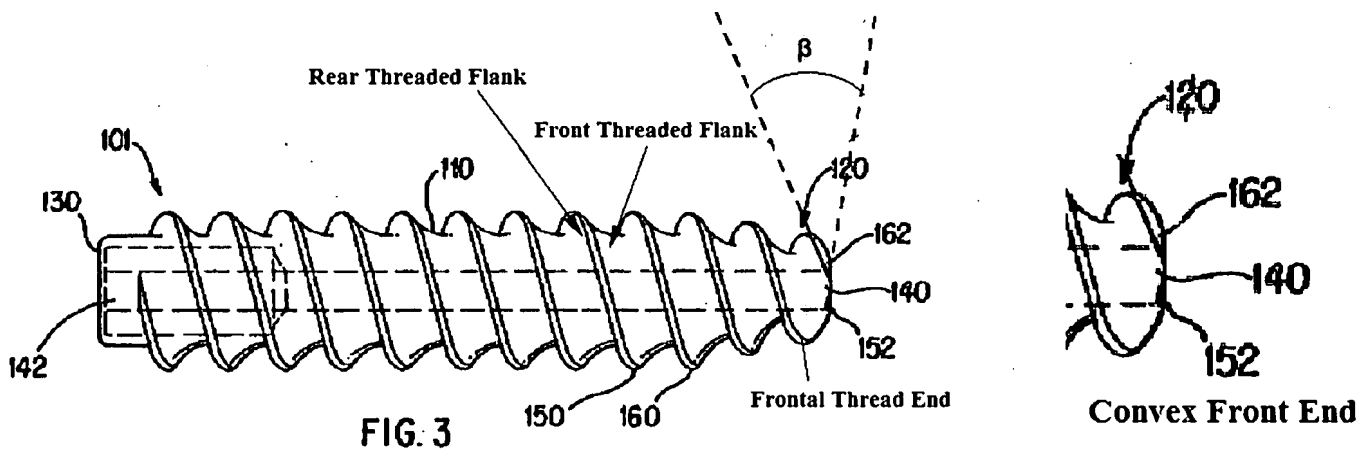
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 9, 13, 14, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Boucher et al. (US Pat. No. 5443509).



Referring to the Figure 3, Boucher discloses a bone screw having a longitudinal axis and a threaded shaft comprising a cylindrical shank 110 and a threaded section, having an external diameter. The threaded section has a frontal thread end and a thread profile, wherein the thread profile has a front threaded flank directed towards the frontal end, a rear threaded flank, and a flank angle β . The threaded section has

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multiple threads and preferably a double threaded design consisting of threads 150 and 160. It is also disclosed that threads 150 and 160 can consist of sharp edges to cut threads as the screw advances (Column 3, Lines 40-43). Threads 150 and 160 terminate at the tip 120, resulting in a knife like element with cutting edges 154 and 164 at the frontal thread end. The cutting edge goes around the shaft 110 helically and is curved convexly at the tip 120. Also, when viewed from the tip 120 (Figure 4) the cutting edges 164 and 154 extend radially from the shaft 110, and then continue in a sickle-shape with the cutting edges disposed on the outer edge. Furthermore, the front end or tip portion 120, which has a convex shape as seen in the enlarged view of tip 120, coincides with the frontal thread end.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5-8, 10-12, and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Boucher et al. (US Pat. No. 5443509).

Boucher discloses the claimed invention except for the sector angle that the cutting edge encloses, the angle the knife-like element encloses, the cutting angle of the knife-like element, a facet and the angle that it makes with regards to the longitudinal axis. With regard to these claims, it would have been obvious to one having

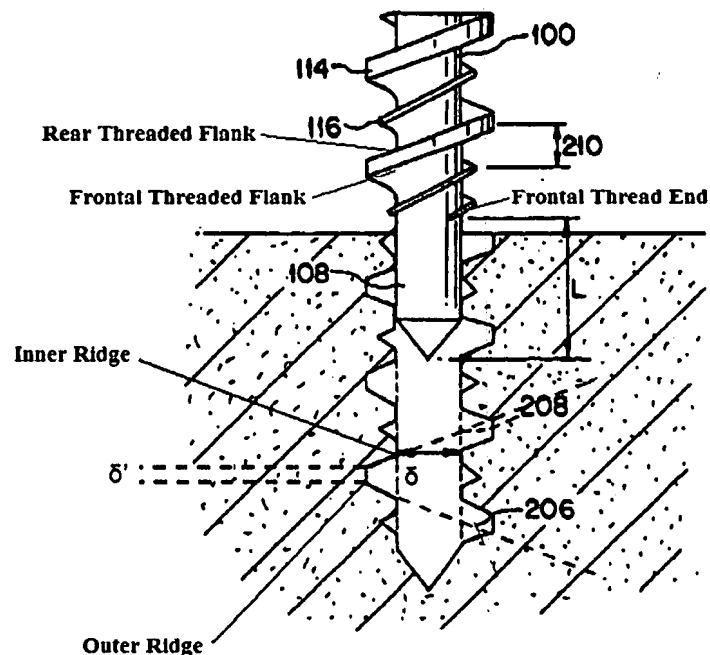
ordinary skill in the art at the time the invention was made to construct the bone screw of Boucher with the angles disclosed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin (US Pat. No. 6749233) in view of Boucher.

Baldwin discloses a medical screw having a longitudinal axis comprising a shaft 102 with a threaded portion 106 with an external diameter, a frontal thread end of threaded portion 106 as seen in Figure 3 on the next page, and a thread profile. The thread profile has a front threaded flank, a rear threaded flank, and a flank angle β . The threaded portion 106 is composed of multiple threads 114 and 116. Furthermore, Figure 3 shows the medical screw of Baldwin entering into a pre-tapped hole with threads to match, thus leaving a profile of the screw. The profile shows threads with an inner ridge with flank angle δ near the shaft 102 and an outer ridge with flank angle δ' wherein δ is greater than δ' . Baldwin fails to disclose a knife-like element with a cutting edge at the frontal thread end of the threaded section. Boucher, however, teaches a knife-like element with a cutting edge as previously stated to be able to cut threads as the screw advances as well as cut more aggressively into bone tissue (Column 5, Lines 54-59). Therefore it would have been obvious to one with skill in the art at the time the invention was made to construct the medical screw of Baldwin in view of Boucher so that the driving ability of the screw could be improved to cut more aggressively into denser tissue such as bone.

Claims 1, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin (US Pat. No. 6749233) in view of Boucher.

Baldwin discloses a medical screw having a longitudinal axis comprising a shaft 102 with a threaded portion 106 with an external diameter, a frontal thread end of threaded portion 106 as seen in the figure below, and a thread profile.



The thread profile has a front threaded flank, a rear threaded flank, and a flank angle β . The threaded portion 106 is composed of multiple threads 114 and 116. Furthermore, the figure above shows the medical screw of Baldwin entering into a pre-tapped whole with threads to match, thus leaving a profile of the screw. The profile shows threads with an inner ridge with flank angle δ near the shaft 102 and an outer ridge with flank angle δ' wherein δ is greater than δ' . Baldwin fails to disclose a knife-

like element with a cutting edge at the frontal thread end of the threaded section.

Boucher, however, teaches a knife-like element with a cutting edge as previously stated to be able to cut threads as the screw advances as well as cut more aggressively into bone tissue (Column 5, Lines 54-59). Therefore it would have been obvious to one with skill in the art at the time the invention was made to construct the medical screw of Baldwin in view of Boucher so that the driving ability of the screw could be improved to cut more aggressively into denser tissue such as bone.

Response to Arguments

Applicant contends that Boucher et al. does not disclose a knife like that has sickle shape when viewed from a front end of the screw. However, Boucher et al. discloses that the intersections of surfaces 152, 162 and threads 150, 160 from a knife element with cutting edges 154, 164 (Column 5, Lines 54-56), thus making the thread and the knife element a continuous structure. Since Boucher et al. also discloses the threads themselves having a cutting edge (Column 3, Lines 40-44), the cutting edges 154, 164 extend radially from the center of the screw and then continue with a sickle shape, formed by the cutting edges of the threads 150, 160. Furthermore, a sickle shape is just one of many shapes or forms that one with ordinary skill in the art would find obvious to use when constructing a knife element.

Applicant contends that the threads of Boucher et al. are not sickle shaped. However, sickle shaped is defined as curved and hook like ((sickle. (n.d.).

Dictionary.com Unabridged (v 1.1). Retrieved June 12, 2007, from Dictionary.com

website). The threads 150, 160 do show curved and hook like portions and more specifically where the threads meet with the cutting surfaces.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached Monday-Friday 7:30 am – 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Eduardo Robert can be reached at 571-272-4719. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private Pair only. For More information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact Electronic Business Center (EBC) at 866-217-9197 (toll free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (USA OR CANADA) or 571-272-1000.

A.Y.

6/12/2007



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER